

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: ETHICON INC., PELVIC
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION _____ MDL NO. 2327

THIS DOCUMENT RELATES TO:

ALL WAVE 3 CASES

**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE
TESTIMONY OF DONALD OSTERGARD M.D.**

Recognizing that this Court has previously denied motions to exclude the testimony of Dr. Ostergard under Rule 702, Defendant has narrowly moved here to exclude three separate areas of testimony. Defendants seek to exclude Dr. Ostergard's testimony related to safer alternative designs, the carcinogenicity of polypropylene, and opinions related to warnings, regulatory matters, infection and corporate knowledge. However, Dr. Ostergard's opinions in each of these areas is the product of reliable methodology and therefore, Defendants' motion should be denied.

I. BACKGROUND AND DR. OSTERGARD'S QUALIFICATIONS

Dr. Ostergard is a giant in the field – indeed one of the founding members – of the medical sub-specialty of urogynecology. He graduated with an undergraduate degree in chemistry and then attained a master's degree in anatomy, as well as his medical degree.¹ Following medical school, he completed his residency in obstetrics and gynecology² and has devoted his nearly half-

¹ See Curriculum Vitae of Dr. Donald Ostergard ("Ostergard CV") (attached as Ex. A).

² *Id.*

century work life to clinical practice and academic medicine in the areas of obstetrics, gynecology, and urogynecology.³

Indeed, Dr. Ostergard has been among the select group of physicians who:

- founded the American Urogynecological Society, along with four colleagues;
- participated in the founding of the International Urogynecologic Society and founded its journal: *International Urogynecology Journal*; and
- established a urogynecological fellowship training program so that other physicians can develop the expertise to practice in the field.⁴

In addition, Dr. Ostergard has been on the forefront of publishing textbooks, articles, presentations, and other writings pertinent to his area of expertise.⁵ These writings have regularly been subject to peer review⁶ and include those relating to the treatment of pelvic organ prolapse including surgical options involving the polypropylene mesh at issue here.⁷ He is the recipient of numerous honors and awards, including the prestigious Lifetime Achievement Award, based on the excellence of his clinical practice and research in the field of urogynecology⁸ and is a member of several medical societies in addition to those referenced above where he is a founding member.⁹

Dr. Ostergard has also published and written extensively on a variety of synthetic and natural materials used in pelvic reconstruction surgery dating back to the 1980's, and these works have also been subject to peer review.¹⁰ Concerned about the relatively recent proliferation of

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *See Id.*, Peer Reviewed Book Chapters, No. 28 ("Retropubic Procedures for Surgical Repair of Genuine Stress Incontinence - Sling Operations."); Peer Reviewed Journal Articles, No. 68 ("Delayed Reaction to the Dacron Buttress Used in Urethropepy"); No. 81 ("A Suburethral Sling Procedure with Polytetrafluoroethylene for the Treatment of Genuine Stress Incontinence in Patients with Low Urethral Closure Pressure."); No. 85 ("Correlation of Preoperative Q-tip Tests with Success Using a Suburethral Sling Procedure for Stress Urinary Incontinence..."); No. 100 ("Suburethral Sling Procedure for Genuine Stress Incontinence..."); No. 104 ("Tissue Reaction to Gore Tex TM Suburethral Sling..."); No. 117 ("Postoperative Catheterization, Urinary Retention, and Permanent Voiding Dysfunction Following

surgical procedures being developed, marketed and sold by medical device manufacturers, and the introduction of untested and unproven technologies for use in female pelvic reconstruction, Dr. Ostergard has spent the last several years researching and studying these products and procedures. Dr. Ostergard has published multiple peer reviewed articles specifically relating to polypropylene mesh grafts used in pelvic reconstruction in respected medical and scientific journals and has served on important committees related to the same.¹¹

Dr. Ostergard has also performed thousands of surgical procedures over the course of his medical career.¹² In so doing, he has used a variety of synthetic and biologic materials in pelvic reconstruction, including but not limited to polypropylene mesh, and has taught countless residents and fellowship trainees the techniques to do likewise. In his surgical practice he has had occasion to remove polypropylene mesh devices from patients and has treated their mesh-related complications. Dr. Ostergard also has extensive experience with studies using scanning electron microscopy ("SEM").¹³

With little doubt, Dr. Ostergard is fully qualified to proffer the opinions in his expert reports and in his deposition testimony. He is a true pioneer in his area of expertise and there may be no individual so well-qualified.

II. LEGAL STANDARD

Polytetrafluoroethylene Suburethral Sling Placement."); No. 119 ("Banked Human Fascia Lata for the Suburethral Sling Procedure...."); 127 ("Update on the utilization of grafts in pelvic reconstruction surgeries."). Dr. Ostergard has also prepared several poster presentations, abstracts, films and videos relating to these subjects, again dating back to the 1980's. *See*, Ex. 2, Abstracts, No. 47; No. 48; No. 51; No. 54; No. 62; No. 65; No. 70; No. 74; No. 89; No. 95; **Ex. 2**, Films, Videos and Other, No. 11, No. 12

¹¹ *See* Ex. M, Peer Reviewed Journal Articles, No. 129 ("Polypropylene Mesh Grafts in Gynecology" in *Obstetrics and Gynecology*

¹² *Id.*

¹³ *Id.*

Plaintiffs will not repeat in full the applicable standards relating to the admission of expert testimony as this Court is well-versed in those standards. For the purposes of this opposition, as this Court has recognized “[t]he proponent of expert testimony does not have the burden to “prove anything” but must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.”¹⁴ Additionally, this Court has noted it “need not determine that the proffered expert testimony is irrefutable or certainly correct” – “[a]s with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’”¹⁵

III. ARGUMENT

Defendants seek to exclude Dr. Ostergard’s opinions related to testimony related to five areas claiming:

- Dr. Ostergard’s safer alternatives opinions are not reliable because they are not supported by sufficient facts or data.¹⁶
- Dr. Ostergard’s carcinogenicity opinions should be excluded.¹⁷
- Dr. Ostergard’s infection opinions should be excluded as irrelevant.¹⁸
- Dr. Ostergard is not qualified to testify about FDA regulatory requirements or what warnings should be included in an IFU.¹⁹

¹⁴ *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013) (quoting *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998)).

¹⁵ *In re C.R. Bard*, 948 F. Supp. 2d at 601 (quoting *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006)); *see also Maryland Cas. Co.*, 137 F.3d at 783.

¹⁶ Def’s. Br. At 2

¹⁷ *Id* at 5.

¹⁸ *Id.* at 7

¹⁹

- Dr. Ostergard's opinions on Ethicon's intentions and narrative review of corporate documents are inadmissible.²⁰

Plaintiffs do not intend on offering testimony on the carcinogenicity of the polypropylene in Gynemesh and therefore will not oppose Defendants motion on that particular issue. Likewise, Plaintiffs do not intend to offer Dr. Ostergard's opinions on the "state of mind" of Ethicon. Plaintiffs vigorously contest each of the remaining items Defendants seek to exclude.

A. Dr. Ostergard's opinions on safer alternative mesh designs are reliable.

While Defendants ostensibly seek to exclude Dr. Ostergard's opinions related to alternative safer mesh designs, they focus their argument on excluding testimony supporting the notion that "Polyform, Popmesh, Pelvitex, and Timesh" devices are safer alternative designs.²¹ Moreover, Defendants state, "He proposes to testify that there are safer alternatives to Gynemesh, PS, specifically discussing in his report four other meshes that he asserts have favorable characteristics: Polyform, Popmesh, Pelvitex, and Timesh." However, Dr. Ostergard has never contended and will not testify that ANY of these four devices are a safer alternative device to the Gynemesh PS. According to Dr. Ostergard,

Q. It is not your opinion that those are suitable alternative meshes to Gynemesh PS, True?

A. No, those were just ones that were compared to these particular studies.²²

Instead, Dr. Ostergard used those devices to make a point of comparison about specific characteristics of mesh. However, none of these devices contain all of the characteristics that would make them a proper suitable alternative design (i.e. larger pore, lower density, lower weight,

²⁰ Id. at 9.

²¹ Id. at 1.

²² Deposition of Dr. Donald Ostergard dated March 9, 2016 at 120:18-21 at Def's Ex C.

less stiffness, and nondegradable polypropylene). Thus, the premise underlying this motion—that these four devices are suitable alternative devices- is incorrect negating the point of their motion.

To further underscore this point, Defendants criticize Dr. Ostergard’s reliance on two medical articles, Jones and Huebner.²³ Defendants claim Dr. Ostergard’s opinions on alternative design are unreliable because the Jones article demonstrated that these other meshes were subject to irreversible deformation at significantly lower loads” and the Huebner article “does not offer any comparison of Gynemesh stiffness to that of Polyformm Pelvitex, or Timex [sic].”²⁴ Yet, Dr. Ostergard was not trying to make the point that Defendants attack. Instead he was simply discussing the notion Gynemesh when compared to other products already on the market was heavier weight and stiffer. Lower weight and decreased stiffness are two qualities that Dr. Ostergard believes are necessary as part of an alternative design. However, even assuming *arguendo* that Defendants are correct that Dr. Ostergard was suggesting one of these as a suitable alternative, deformation at lower loads is not necessarily a bad thing- so long as the device can handle the loads the body requires.

Importantly, Defendants motion ignores many statements within his report and articles cited by Dr. Ostergard that support his conclusions that mesh designs with lower weight, greater porosity, lower density, and lower stiffness that are not degradable are able to reduce the risks from that of the Gynemesh and only in this combination make a safer alternative design. Some of these statements include:²⁵

- In 2013, Liang et al studied vaginal degeneration in primates with meshes of increased stiffness using Gynecare Gynemesh PS compared to two other lower stiffness meshes. The stiffer Gynecare Gynemesh PS had the greatest negative impact on vaginal histomorphology and composition. This mesh caused a substantial thinning of the vaginal smooth muscle layer, increased apoptosis in the area of the mesh fibers, decreased

²³ Attached to Def’s Br. At Ex. D and E.

²⁴ Def’s Br. At 3-4.

²⁵ See Rule 26 Report of Dr. Donald Ostergard at 13-14 attached at Ex. B

collagen and elastin content and increased collagenase activity. Glycosamineglycan, a marker of tissue injury, was highest with Gynecare Gynemesh PS. This mesh induced a maladaptive modeling response consistent with vaginal degeneration. (Liang et al. BJOG 2013;120:233-43)

- In 2013, Feola et al. studied deterioration in biomechanical properties of the vagina after implantation of a high-stiffness mesh in the form of Gynecare Gynemesh PS compared to two lower stiffness meshes. The greatest reduction in vaginal contractility occurred with Gynecare Gynemesh PS at 80% reduction and the tissue contribution to the passive mechanical behavior of the mesh-vaginal complex was drastically reduced for Gynecare Gynemesh PS. (A Feola et al. BJOG 2013;120:224-32)
- In 2013, Edwards found that newer fabricated meshes were uniaxially less stiff than Gynecare Gynemesh PS. (SL Edwards et al. J Mech Behav Biomed Mater 2013;23:53-61)
- In 2014, at the joint AUGS/IUGA meeting, Moalli in a workshop handout states that Gynemesh PS, a heavier weight, lower porosity, stiffer mesh, causes a 60% decreased in thickness of the vaginal muscularis, a 170% increase in apoptotic cells, and decreased collagen in the grafted vagina. The stress shielded vagina “then undergoes maladaptive remodeling characterized by degeneration and atrophy (loss of collagen, elastin and muscle)”. “Prosthetic devices that are significantly stiffer than the native tissue they are designed to augment are associated with increased rate of long term complications”. (augs-iuga2014.org/d/do/3031)

Likewise, important articles like those by Ostergard himself, Dr. Klausterhalfen, Dr. Klinge and many others (totaling more than 600 articles personally collected and reviewed by Dr. Ostergard) support his overall opinions that it is the combination of factors that make a suitable alternative. Importantly, Ethicon has not challenged these views on alternative designs.

Thus, because Defendants incorrectly assert what his opinions are and the basis for the motion to exclude is fundamentally incorrect, Defendants’ motion should be denied.²⁶

²⁶ In the instant case, Dr. Ostergard explained that he has studied and is familiar with the published and peer-reviewed literature relating to polypropylene implants, which in itself is a recognized, reliable scientific methodology. See *Huggins v. Stryker Corp.*, 932 F.Supp.2d 972, 993 (D. Minn. 2013) (“As an initial matter, there does not seem to be a real dispute about the legitimacy of the experts’ ‘methodology,’ which is to review the medical literature and draw a conclusion about what teachings or red flags were contained within the literature.”); also see *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) (“Trained experts commonly extrapolate from existing data.”).

However, Dr. Ostergard does not just rely on what he read - he actually did the research himself. One of the hallmark factors of scientific reliability for purposes of Daubert and its progeny is peer review and publication, and Dr. Ostergard's work has survived this gauntlet. See *Daubert*, 509 U.S. at 593-94, 113 S.Ct. at 2797 (“[S]ubmission to the scrutiny of the scientific community is a component of ‘good science,’ in part because it increases the likelihood that substantive flaws in methodology will be detected.... The fact of publication (or lack thereof) in a

B. Dr. Ostergard's opinions on mesh design is relevant and admissible.

Defendants next seek to exclude the following opinions "[t]o the extent that those cases do not involve infection:"

- "The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages." Ex. B, Ostergard Report at 2-3, ¶ 7(a).
- "With loss of PP due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence . . . which increases the inflammatory reaction and intensity of fibrosis." *Id.* at 3, ¶ 7(d).
- "Predominate infection/inflammation was noted in 2007 in explanted samples from Dr. Cosson's series of patients." *Id.* at 3, ¶ 7(g).
- "The large surface area promotes wicking of fluids and bacteria and is a 'bacterial super highway' which provides a safe haven for bacteria which attached themselves to the mesh during the insertion process." *Id.* at 3, ¶ 7(h).
- "The size of the mesh placed equates to a very large surface area with many places for bacteria to hide, protected from host defenses." *Id.* at 4, ¶ 8(a).

Yet, these opinions are not opinions on infection. These opinions are focused on specific defects within the design of the mesh that create all manner of complications including erosion, pain, and inflammation: with or without infection. Likewise, Plaintiffs experts, including but not limited to Dr. Ostergard and Dr. Guelcher describe how these particular design elements lead to degradation of the mesh and complications.

Finally, issues on relevance should be determined on a case by case basis at the time of trial.

Thus, Defendants motion should be denied here as well.

peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.") . Ethicon conveniently forgets that Dr. Ostergard has published his opinions in peer reviewed literature on this issue. Moreover, Dr. Ostergard has been cited by manufacturers of other mesh devices for his publications related to alternative design, ie. lighter weight larger pored meshes.

C. Dr. Ostergard is qualified to opine on the information contained in Defendants' IFUs.

Defendants' argument that Dr. Ostergard is not qualified to testify about the adequacy of warnings provided with Defendants' products is without merit. Dr. Ostergard's qualifications and process of evaluating the adequacy of the instructions for use ("IFU") for the products manufactured by Defendants is similar to the qualifications and process that this Court approved in *Huskey v. Ethicon*. Addressing a Daubert challenge against Dr. Rosenzweig's warning opinions, this Court stated:

In his expert report, Dr. Rosenzweig states that he has reviewed "numerous" IFUs for a "variety of products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the device." . . . Further, as a urogynecologist, Dr. Rosenzweig is qualified to opine about the risks of the TVT-S and pelvic mesh surgery and whether those risks were adequately expressed on the TVT-S's IFU. I therefore FIND that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT-S's product warnings and marketing materials.²⁷

Similarly, this Court approved Dr. Blaivas to testify about warnings for DEFENDANTS products in *Tyree v. Boston Scientific Corp.*:

[A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-S and whether those risks were adequately expressed on the TVT-S's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warnings and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-S was when the warnings were published.²⁸ P

²⁷ *Huskey v. Ethicon, Inc.*, 2014 WL 3362264 at *5 (S.D. W. Va. July 8, 2014)).

²⁸ *Tyree*, 2014 WL 5320566 at * 47 (quoting *Huskey*, 2014 WL 3362264 at *20). See also *Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F. Supp. 2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet Drug MDL PTO 1332*, where the MDL court concluded physicians are "qualified to render an opinion as to the labels' completeness, accuracy, and . . . the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits . . . are or were at the time the labeling was published." *In re: Diet Drug MDL PTO 1332* at p. 27-28); *Grobelny v. Baxter Healthcare Corp.*, 2008 WL 2186417, *2 (D.N.J.2008) (holding that toxicologist/pharmacologist could not testify as to adequacy of the warning because "he has no experience with pharmaceutical labels because...he is neither a practicing physician nor a licensed pharmacist," but that the plaintiff's treating physician could testify as to his understanding of the risks of drug in question, and that treating physician's testimony would be helpful for

In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011), the drug manufacturer argued that the plaintiffs' proffered experts, both obstetrician-gynecologists ("OB/GYN"), were not qualified to offer opinions regarding the adequacy of its labeling, and further that their opinions were not based on any reliable methodology. The Court rejected its argument, and held instructively as to one of the OB-GYN experts as follows:

As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]...and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualified to render an opinion as to the drug label's completeness and accurateness. *See id.*....

Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.²⁹

Dr. Ostergard is qualified to provide opinions about the risks associated with Defendants' Gynemesh and "whether those risks were adequately expressed" in the IFU in place at the time of Plaintiffs' surgery and "the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits."

Defendants' claim that Dr. Ostergard's opinions regarding the inadequacies in the IFUs

the jury to understand "the characteristics of, and the ordinary knowledge common to, the prescribing physician," as required under New Jersey law).

²⁹ The same holding with respect to the Plaintiffs other proffered OB-GYN expert (Anthony Disciullo) – based on his extensive clinical experience and review of peer-reviewed literature and company documents, he was qualified to offer opinions as to the adequacy of the drug warning label, and his opinions were reliable.

lack a reliable basis misrepresents his reports, ignores the bases for his opinions and the methodology employed to reach those opinions. Contrary to Defendants' assertion, Dr. Ostergard's opinions concerning the inadequacy of the IFU have a reliable basis including the medical literature addressing complications arising from mesh slings and pelvic organ prolapse mesh products.³⁰

D. Defendant's claimed narrative opinions are not inadmissible.

Defendants' argument regarding Dr. Ostergard's supposed "narrative summaries" is based upon the faulty premise that all narrative testimony is prohibited. Courts have broad discretion which would allow testimony in narrative form, and any such objections should only be enforced at the time of trial in the context of specific documents and expert testimony, not by the way of a *Daubert* motion. See *In re Yasmin and YAZ (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, 2011 WL 6302287, *13 (S.D. Ill. Dec. 16, 2011) (finding that as to drug manufacturer's argument regarding narrative testimony, courts have broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would helpful to the jury); *United States v. Pless*, 982 F.2d 1118, 1123 (7th Cir. 1992) ("Fed. R. Evid. 611(a) provides district judges with authority to allow testimony in narrative form rather than as answers to specific questions [citations omitted], and we ourselves have said that 'there is ... nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality' (*United States v. Garcia*, 625 F.2d 162, 169 (7th Cir. 1980)).").

³⁰ *Id.*

In addition, Dr. Ostergard should be allowed to testify about facts from which the jury can infer intent. *See, e.g., DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) (holding an engineer could testify *as an expert* “that reducing the padding saved a particular amount of money ... [and] that [the manufacturer's] explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify *as an expert* that [the manufacturer] had a particular motive”); *Wells v. Allergan, Inc.*, 2013 WL 7208221, *2 (W.D. Okla. Feb 4, 2013) (holding that plaintiff’s expert could testify about facts from which the jury could *infer* intent). Here, Dr. Ostergard will not be guessing as to what Defendants thought or knew. Instead, Dr. Ostergard will rely upon Defendants’ internal documents to explain what knowledge was available to Defendants and its employees, what information Defendants *should* have known as a manufacturer of mesh devices, and both what the company *should* have done upon learning such information and what the company's own documents factually demonstrate that the company *did* do during the life of Gynemesh. Additionally, Dr. Ostergard is not simply mimicking the content of the documents themselves. Many of the documents require medical explanation for an understanding of their significance. Dr. Ostergard is well qualified to render such testimony and has a sufficient factual basis on which to rest his opinions. Accordingly, should Defendants feel that Dr. Ostergard has departed from an analysis of the facts and entered the realm of speculation during his testimony, Defendants may object at trial. But requesting such a ruling at the pretrial stage is simply premature.

IV. CONCLUSION

For the forgoing reasons, Defendants’ motion should be denied.

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Respectfully Submitted,

By: s/Fidelma L. Fitzpatrick
Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com

Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Fidelma L. Fitzpatrick
Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com
Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Attorneys for Plaintiffs